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Phillippe Doullet
One Holyoke Lane
Stony Brook, New York 11790

Re: Docket No. 83P-0404

Dear Mr. Doullet:

This responds to your November 8, 1983, petition requesting that cosmetic talc be labeled with an asbestos warning statement, information on asbestos particle size, and the proportion of talc impurities in the product.

You assert that, because the mining of talc almost invariably includes the mining of asbestos as well, cosmetic talc may contain significant amounts of asbestos particles that present an inhalation hazard to humans. Also, you cite references to substantiate that significant amounts of asbestos have been found in commercial talc samples, that asbestos inhalation is hazardous to humans, and that asbestos contaminants in talc will produce toxicological responses when inhaled.

FDA recognizes that asbestos inhalation over extended periods is hazardous to humans. The agency is also aware that some cosmetic talc produced in the 1960s and early 1970s did contain asbestiform minerals. However, your petition has not persuaded us that the cosmetic talc that is presently being produced contains significant amounts of asbestiform minerals.

During the early 1970s, FDA became concerned about the possibility that cosmetic talc did contain significant amounts of this material. The agency received several reports about such contamination. However, at that time, the analytical procedures for determining asbestos in talc were not fully developed, and most of the analytical work was conducted without scientific agreement as to which methods were well-suited for the identification of asbestiform minerals in talc. Consequently, FDA considered all analytical results to be of questionable reliability. This assessment proved to be correct because many questions were subsequently raised about results reported in the literature in the early 1970s (see enclosed copy of National Bureau of Standards Special Publication 506 entitled "Misidentification of Asbestos in Talc"). Because of the questionable nature of the analytical results, the agency was not able to assess reliably the levels of asbestiform minerals in cosmetic talc then in the marketplace.

83P-0404

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Under these circumstances, FDA decided that the most appropriate actions that it could take to protect the public health would be to make the reports public and to request assistance from the affected industry in developing acceptable analytical procedures. This approach apparently has led to considerable improvement in the quality of this talc.

After FDA took these actions, many cosmetic manufacturers began to analyze their talc for asbestiform minerals as part of their quality control programs, and talc suppliers began to sell higher purity talcs to the cosmetic industry. By 1976, asbestos analytical methodology was sufficiently developed that the Cosmetic, Toiletry, and Fragrance Association (CTFA) could issue a specification (copy enclosed) for cosmetic talc. This specification required that such talc be free of fibrous amphibole (e.g., asbestos in the form of asbestiform tremolite) using a CTFA method of analysis that is capable of detecting 0.5 percent of amphibole asbestos. This specification contributed to the continued improvement of cosmetic talc quality.

In addition, FDA surveillance activities that were conducted in the latter portion of the 1970s showed that the quality of cosmetic talc had significantly improved, and that even when asbestos was present, the levels were so low that no health hazard existed. Our scientists recently reviewed data from these surveillance activities and concluded that the risk from a worst-case estimate of exposure to asbestos from cosmetic talc would be less than the risk from environmental background levels of exposure to asbestos (non-occupational exposure) over a lifetime.

Consequently, we find that there is no basis at this time for the agency to conclude that there is a health hazard attributable to asbestos in cosmetic talc. Without evidence of such a hazard, the agency concludes that there is no need to require a warning label on cosmetic talc.

FDA should also point out that, in reviewing your petition, we found several problems with the information on which you relied. The publication "Asbestiform Impurities in Commercial Talcum Powders," which you cite in your petition, appears to contain a number of significant errors that lead us to question the accuracy of the findings that were reported. For your information, we have enclosed a copy of a June 8, 1973, rebuttal of this publication that was written by the Chief Mineralogist of the Colorado School of Mines Research Institute in Golden, Colorado. Also, your petition's 1978 book reference to the Mt. Sinai School of Medicine findings is too old to reflect present contamination levels. Further, we are not convinced that the Mt. Sinai findings pertained to cosmetic talc. Your reference states that common commercial talcs were analyzed, but it does not specify whether these commercial talcs were industrial grade or cosmetic talc.

For all of these reasons, your petition is denied. This denial is without prejudice to the future filing of a petition on this matter, accompanied by all relevant data in support of the petition.

Sincerely yours,

H. J. W. Sanson

Acting Associate Commissioner
for Regulatory Affairs

Enclosures